Attorney Docket No.: FGRTNZ00200

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Date: January 11, 2010 Signature: _____ (David A. Levine)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/622,437
Confirmation No.:	4971
Filing Date:	July 18, 2003
Inventor(s):	Thomas J. FOGARTY et al.
Title:	EMBOLIZATION DEVICE AND A METHOD OF USING THE SAME
Examiner:	Katherine M. Dowe
Group Art Unit:	3734

Mail Stop Appeal Brief - Patents
Commissioner for Patents
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Washington, D.C. 22313-1450

REPLY BRIEF

Sir or Madam:

Pursuant to 37 CFR 1.193(b)(1), Applicant responds to the new points raised in the Examiner's Answer mailed November 9, 2009 (the two-month date for reply fell on a Saturday, hence the deadline for reply is 11 January 2010 and this Reply Brief is timely filed), as follows:

I. Real Party in Interest

This application is assigned to Thomas J. Fogarty of Portola Valley, California.

II. Related Appeals and Interferences

Assignee filed a Notice of Appeal in the following commonly assigned pending applications:

1) U.S. Patent Application 10/301,061, filed November 20, 2002, entitled DEVICES AND METHODS FOR TREATMENT OF VASCULAR ANEURYSMS. In response to Applicants' Appeal Brief of August 28, 2008, a Non-Final Office Action was issued, in which the Examiner withdrew the finality of the previous Final Office Action and indicated that the arguments filed in Applicant's August 28, 2008 Appeal Brief where fully considered and persuasive, resulting in the previous rejections being withdrawn.
2) U.S. Patent Application 10/293,139, filed November 12, 2002, entitled EMBOLIZATION DEVICE AND A METHOD OF USING THE SAME. In response to Applicants' Appeal Brief of May 19, 2008, a Notice of Allowance was mailed on September 19, 2008.

III. Status of Claims

Claims 1-38 were canceled. Claims 39-59 were rejected. Claims 39-59 are currently under appeal.

IV. Status of Amendment

No amendment was made subsequent to final rejection.

V. Summary of Claimed Subject Matter

The independent claims on appeal are Claims 39, 42 and 59. All noted specification locations, reference characters, and figures below are for exemplary purposes only and are non-limiting.

Claim 39 "a method for filling an abnormal void within the body," see e.g., figures 20 and 22; p. 23: ll. 19-23.

The claim recites attaching a first end of a first space-occupying element (28) of a space-occupying device (24) to a second end of a second space-occupying element (30) of the space-occupying device (24), (see e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 21, l. 18 to p. 22, l. 4). The claim also recites wherein the first end of the first space-occupying (28) device is rotatably attached to the second end of the second space-occupying device (30) (e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 13, ll. 1-4).

The claim also recites placing in a void (aneurysm 4) within the body a catheter (80) having a distal exit (82), the distal exit placed at a treatment site (sac 10), (see e.g., figure 20; p. 23, ll. 20-22).

The claim recites passing the first space-occupying element (28) through the catheter (80) and distal exit (82), (see e.g., figures 20; p. 7, ll. 19-21; p. 23, ll. 22-23). The claim recites, the space-occupying device (24) comprising a device volume, (see e.g., figures 10 and 20; p. 7, l. 21) and a coating wherein the coating comprises a binding agent (132), wherein the binding agent reduces the flexibility of the space-occupying device. (see e.g., figure 15; p. 17, ll. 10-13, 21-22; p. 24, ll. 17-19)

The claim also recites, passing the second space-occupying element (30) through the catheter (80) and distal exit (82) and deploying the device (24) into the treatment site (sac 10). (see e.g., figures 20; p. 7, ll. 19-21; p. 23, ll. 22-23).

Claim 42 "a method for filling an abnormal void within the body," see e.g., figures 20 and 22; p. 23: ll. 19-23.

The claim recites, coating a space-occupying device with a binding agent (132), wherein the binding agent is configured to reduce the flexibility of the space-occupying device, (see e.g., figure 15; p. 17, ll. 10-13, 21-22; p. 22, ll. 13-17; p. 24, ll. 17-19)

The claim recites attaching a first end of a first space-occupying element (28) of a space-occupying device (24) to a second end of a second space-occupying element (30) of the space-occupying device (24), (see e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 21, l. 18 to p. 22, l. 4). The claim also recites wherein the first end of the first space-occupying (28) device is rotatably attached to the second end of the second space-occupying device (30) (e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 13, ll. 1-4).

The claim also recites inserting the first space-occupying element (28) into the abnormal void (aneurysm 4) (see e.g., figures 20; p. 7, ll. 19-21; p. 23, ll. 22-23).

The claim recites "inserting the second space-occupying element (30) into the abnormal void (aneurysm 4) wherein the first space-occupying element (28) is rotatably attached to the second space-occupying element (30) (e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 13, ll. 1-4).

Claim 59 "a method for filling an abnormal void within the body," see e.g., figures 20 and 22; p. 23: ll. 19-23.

The claim recites attaching a first end of a first space-occupying element (28) of a space-occupying device (24) to a second end of a second space-occupying element (30) of the space-occupying device (24), (see e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 21, l. 18 to p. 22, l. 4). The claim also recites wherein the first end of the first space-occupying (28) device is rotatably attached to the second end of the second space-occupying device (30) (e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 13, ll. 1-4).

The claim recites, "wherein the first end of the first space-occupying device (24) is rotatable more than 180° with respect to the second end of the second space-occupying device" (See e.g., figure 3a)

The claim also recites placing in a void (aneurysm 4) within the body a catheter (80) having a distal exit (82), the distal exit placed at a treatment site (sac 10), (see e.g., figure 20; p. 23, ll. 20-22).

The claim recites passing the first space-occupying element (28) through the catheter (80) and distal exit (82), (see e.g., figures 20; p. 7, ll. 19-21; p. 23, ll. 22-23). The claim recites, the space-occupying device (24) comprising a device volume, (see e.g., figures 10 and 20; p. 7, l. 21) and a binding agent (132), wherein the binding agent

reduces the flexibility of the space-occupying device. (see e.g., figure 15; p. 17, ll. 10-13, 21-22; p. 24, ll. 17-19)

The claim also recites, passing the second space-occupying element (30) through the catheter (80) and distal exit (82) and deploying the device (24) into the treatment site (sac 10). (see e.g., figures 20; p. 7, ll. 19-21; p. 23, ll. 22-23).

VI. Grounds of Rejection to be Reviewed on Appeal

Whether claims 39-59 are unpatentable under 35 U.S.C. 103(a), over Berenstein et al., (U.S. Pat. No. 6,458,119) in view of Ritchart (U.S. Pat. No. 4,994,069).

VII. Argument

Appellant respectfully notes that the examiner's Answer to the Appeal Brief ("Answer") of 9 November 2009 vacillates between backpedalling from the fundamental argument made in the previous Office Actions - but still argues the primary motivation to combine, which is not supported by the references - and puts forth a new argument regarding the examiner's intended use of the word "binding", which was not previously raised, yet still does not provide sufficient motivation to combine.

First, on Page 5, the Answer states that the Berenstein et al. (U.S. Patent No. 6,458,119) teaches that the fibers or "filaments" (602) "are capable of minimally reducing the flexibility of the space-occupying device as arranged in Figure 6B compared to the arrangement in Figure 6C." The Examiner's argument in past Office Actions, and again suggested by the above-quoted passage, has been founded on this concept that the filaments (602) reduce flexibility of the device taught by Berenstein et al. However, this is a concept created by the examiner, and not taught anywhere within Berenstein et al. nor obvious to one having ordinary skill in the art. The examiner's argument even goes against the teaching of Berenstein et al.

Nowhere in Berenstein et al. is it suggested that the filaments (602) provide or are even capable of any mechanical or structural support. The examiner has made this argument with no evidentiary support. Not only does Berenstein et al. never mention or imply in the text that the filaments (602) would provide any binding between the chain links, Figure 6B even shows that the filaments (602) have a significant amount of slack between links of the chain. In Figure 6C, the filaments (602) are not even connected between the links, further exemplifying that Berenstein et al. never contemplated the filaments (602) providing any binding force between the links. Berenstein never even insinuates that the fibers would become taught when the chain is rotated - and therefore would never even be placed in a tensile condition, thus never providing any mechanical resistance between, nor binding of, the links of the device.

In fact, Berenstein et al. teaches away from the use of any binding agent, let alone the filaments (602). At col.7, lines 37-52, Berenstein et al. states that "[e]ach of the variations discussed...is an extremely soft and flexible device...exert[ing] little if any

radial force on the blood vessels into which they are placed... They are sufficiently flexible...that they may be carried by blood flow after ejection from the ...the catheter... The fluid-like properties of the device enables it to conform to the complex geometry of certain fragile, abnormal blood vessels, and in so doing, minimize the risk of causing trauma to or even perforation of those blood vessels. Such flow properties also enable placement of the inventive device at sites in the vasculature currently unreachable by catheterization." Therefore, any agents causing increased rigidity, or binding, of the device would oppose the function of softness and flexibility stated in the above-quoted passage.

Even the examiner's Answer seems to be backing away from the argument, yet still puts it forth, by stating the filaments (602) are "capable of minimally reducing the flexibility" and "are not designed for significantly reducing the flexibility of the...device." (emphasis added) However, the Answer still fails to admit that the filaments (602) are not designed at all for reducing the flexibility of the device, nor point to where Berenstein et al. teaches the filaments (602) reduce flexibility of the device.

Second, the examiner's Answer states that "the examiner's intent was not to interpret the fibers (602) as the claimed coating comprising the binding agent designed to reduce the flexibility of the space occupying device. Rather, the fibers are a binding agent in the sense that they help induce clot formation and help bind a thrombus." Not only was this argument never mentioned in past office actions, it is not a logical connection to suggest that a clot-forming element, such as the fibers (602) of Berenstein et al., should be replaced with or supplemented by the rigid coating 36 of Ritchart et al. Also, Ritchart et al. never mentions that the coating 36 is intended to bind to thrombi, and even teaches using the coating inside of the device, which would minimize exposure to body fluids from which clots can form and thrombi can bind. Further, applying a rigid encapsulating material to the filaments (602) of Berenstein et al. would reduce the flexibility of the filaments (602) - which clearly extend radially from the device, as shown in Figures 6B and 6C - therefore impeding the ability to pack the device into a catheter for delivery and deliver the device through the catheter.

In fact, the examiner's most recent Final Office Action of 29 October 2008 states on page 2 that the "binding agent 602 would cause the chain coil to **exhibit less flexibility** compared to if it were not present. However, Berenstein does not disclose the binding agent is a coating. Ritchart discloses ... a binding agent 36." (emphasis added) This Final Office Action explicitly argued that the filaments (602) of Berenstein et al. teach a "binding agent" which cause the device to "exhibit less flexibility", therefore improperly providing the motivation for the examiner to combine the rigid coating 36 of Ritchart with Berenstein et al., which the examiner implied also reduces flexibility and also explicitly called a "binding agent". Furthermore, the term "exhibit less flexibility" is used to describe the alleged "binding agent 602" of Berenstein et al. in the Office Action of 11 January 2008, and the Final Office Action of 27 April 2007, the other two office actions in which Berenstein et al. is cited. Furthermore, none of the previous Office Actions mentioned thrombi or clots forming on the device.

The examiner's Answer is reversing course and now arguing that the examiner previously meant to use "binding agent ... in the sense that they help induce clot formation and help bind a thrombus within the aneurysm," as is proffered on page 5 of the Answer. The Applicant has not had a chance to reply to try to resolve this line of argument from the examiner outside of this Appeal, but respectfully feels the argument does not provide a *prima facie* basis for a rejection, regardless.

Furthermore, the examiner's Answer repeatedly argues a motivation to straighten the Berenstein et al. device during delivery as a reason to combine with Ritchart's device, but this argument goes completely against the teaching of Berenstein et al. to a device that can be "extremely soft and flexible" to navigate tortuous passages within a catheter. (Berenstein et al., col. 7, lines 38-38.)

For example, the examiner's Answer argues that combining the rigid coating 36 of Ritchart with the device of Berenstein et al. would improve the delivery process of the device through the catheter by keeping "the device relatively straight while being passed through the catheter" as " Ritchart clearly teaches". However, this argument ignores that Berenstein et al. explicitly states in col. 9, lines 49-52, that the device "will move through tortuous pathways ... in the catheter with significantly more ease than would be observed

by the other coils." The function of the device of Berenstein et al. is to allow tortuous navigation of the soft and flexible device, not impede such navigation by rigidly holding the device straight by a rigid coating, as Ritchart teaches in col. 3, lines 14-15.

Berenstein et al. even goes so far as to directly compare its device to Ritchart's device stating, "the significant difference between a preferred embodiment of this inventive coil and similar commercial coils of the type discussed in Ritchart et al. [is] how much more flexible is the inventive coil than the other coils." (Berenstein et al., col. 8, lines 58-62.)

REMARKS

The references mentioned above fail to disclose the claimed invention. Appellant therefore, respectfully submits that the pending claims are not properly rejected under § 103(a).

For these reasons, and the reasons stated in the Appeal Brief, Appellant submits that the final rejection should be reversed.

Applicant believes all outstanding issues raised in the previous Office Action are addressed herein and that the claims are in condition for allowance.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **FGRTNZ00200**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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